## REMARKS

Claims 1-3, 6, and 12-14 were pending. Claims 1-3 and 12-14 are currently amended; claims 4-5 and 7-11 are canceled; claim 6 is previously presented; and claims 15-40 are added. Therefore, claims 1-3, 6, and 12-40 are pending.

A Request for Continued Examination is filed herewith.

**Discussion of Amended and New Claims**

The following recitations appear in some or all of claims 1, 24, and 31:

"the implant is positionable in a coronary sinus in the first flexible configuration, such that a proximal portion of the implant is positioned in a proximal part of the coronary sinus, and a distal portion of the implant is positioned in a distal part of the coronary sinus, wherein the proximal part is closer to the ostium of the coronary sinus than is the distal part." Support for this recitation is found in, for instance, Figure 1.

"a forming member, coupled to the control mechanism and to the implant, the forming member extending longitudinally along at least a portion of the implant." Support for this recitation is found in, for instance, Figures 9A and 9B.

"when the implant is positioned in the coronary sinus, and the forming member is advanced distally with respect to the coronary sinus, the curvature of the implant changes, thereby altering a shape of the mitral valve annulus." Support for this recitation is found in, for instance, paragraph [0042].

Applicant has added new claims 15-40. Support for claims 15-19 is found in, for instance, original claims 7-11. Support for claim 20 is found in, for instance, the specification, at paragraph 130. Support for claims 21-23 is found in, for instance, claims 1, 12, and 13. Support

for claims 24 and 25 is found in, for instance, the specification, at paragraph 42. Support for claims 26 and 28 is found in, for instance, claim 12. Support for claims 26 and 39 is found in, for instance, the specification, at paragraph 20. Support for claims 27-28 and 33-34 is found in, for instance, claim 12. Support for claims 29-30 and 35-36 is found in, for instance, Figure 2A. Support for claims 31 and 38 is found as in, for instance, claim 1. Support for claim 32 is found in, for instance, Figure 1. Support for claim 40 is found in, for instance, the specification, at paragraph 38.

No new matter has been added.

**Previously Allowable Subject Matter (Claims 13 and 14)**

The Examiner noted that "Applicant failed to make claim 13 in proper independent form (which was previously indicated as allowable subject matter) because all limitations of intervening claim 12 were not included."

Claim 13 is currently amended to add the subject matter recited in claim 12 as reviewed in the Office Action dated July 27, 2007, when the Examiner indicated that claims 13 and 14 would be allowable if rewritten in independent form.

**Claim Rejections under 35 USC §112, Second Paragraph**

The Examiner rejected claims 13-14 as lacking antecedent basis for "the flexible member."

Claim 13 is currently amended to provide proper antecedent basis.

**Claim Rejections under 35 USC §§102 and 103**

Alferness et al. (USPAP 2002/0169504)

The Examiner rejected claims 1, 2, and 13 as allegedly anticipated by Alferness et al., and he rejected claim 3 as allegedly obvious over Alferness et al.

Claims 1-3, 6, 12-14, as amended, and new claims 15-18 and 20-40 are entitled to at least the February 1, 2001, priority date of U.S. provisional patent application No. 60/265,995 (the '995 application). These claims are fully supported by the '995 application, and therefore antedate Alferness et al., which was filed on, and has an earliest priority date of, May 14, 2001.

Support for the following claim recitations is found in the '995 application at least as follows:

| Recitations of the pending claims | The '995 application |
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| A system, for remodeling a mitral valve annulus, comprising (Claims 1, 22-23, and 31) | Appendix A, page 6, lines 16-18 |
| A system for remodeling a mitral valve annulus, comprising (Claim 13) | Appendix A, page 6, lines 16-18 |
| a delivery catheter (Claims 1, 13, and 22-23) | Specification, page 6, lines 24-27 |
| an implant, detachably carried by the delivery catheter, the implant reversibly movable between a first flexible configuration for delivery to a site adjacent to the annulus of the mitral valve and a | Appendix A, page 13, lines 16-23 |

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| second remodeling configuration for remodeling the mitral valve annulus (Claims 1, 13, and 22-23) | |
| the implant including a guidewire lumen adapted to slideably engage a guidewire (Claims 1, 13, and 22-23) | Appendix A, page 8, lines 16-18 |
| wherein the implant is positionable in a coronary sinus in the first flexible configuration, such that a proximal portion of the implant is positioned in a proximal part of the coronary sinus, and a distal portion of the implant is positioned in a distal part of the coronary sinus, wherein the proximal part is closer to the ostium of the coronary sinus than is the distal part (Claims 1and 31) | Appendix A, Figure 1 |
| wherein the delivery catheter is coupled to a proximal end of the implant (Claims 1 and 22) | Specification, page 6, lines 15-18 |
| the delivery catheter including a control mechanism for selectively adjusting a curvature of the implant in the second remodeling configuration (Claim 1) | Appendix A, Figure 10 |
| a forming member, coupled to the implant and extending longitudinally along at least a portion of the implant (Claims 1 and 31) | Specification, Figures 2A and 2B |
| wherein, when the implant is positioned in the coronary sinus, and the forming member is advanced distally with respect to the coronary sinus, the curvature of the implant changes, thereby | Appendix A, page 24, lines 16-19 |

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| altering a shape of the mitral valve annulus (Claims 1 and 31) | |
| wherein the implant comprises an arc when in the remodeling configuration (Claim 2) | Appendix A, page 25, lines 18-19 |
| wherein a best fit constant radius curve a corresponding to the arc has a radius within a range of from about 10 mm to about 20 mm (Claim 3) | Appendix A, page 25, lines 19-21 |
| further comprising a coating on the implant (Claim 6) | Appendix A, page 30, lines 10-13 |
| wherein the forming member is flexible and has a proximal end attached to the control mechanism and a distal end attached to a distal end portion of the implant, the forming member being slidable for selectively adjusting the curvature of the implant (Claim 12) | Specification, Figures 2A and 2B; Appendix A, page 8, lines 19-20 |
| a control on the catheter for reversibly transforming the implant between the first flexible configuration and the second remodeling configuration (Claims 13 and 23) | Specification, Figures 2A and 2B; Appendix A, page 8, lines 19-20 |
| a flexible member attached to a distal end portion of the implant (Claims 13, 22, and 23) | Appendix A, Figure 10 |
| a rotational coupler along a proximal end portion of | Appendix A, pages 36-38; claim 6 |

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| the implant for applying tension to the flexible member to move the implant to the second, rigid configuration (Claim 13) | |
| wherein the control on the catheter is a thumbwheel for actuating the rotational coupler (Claim 14) | Appendix A, page 36, lines 11-16 |
| wherein the implant comprises an anchor that retains the implant at a deployment site when the implant is in the remodeling configuration (Claim 15) | Appendix A, page 9, lines 18-19 |
| wherein the anchor comprises a distal extension of the implant (Claim 16) | Appendix A, page 24, lines 3-6 |
| wherein the anchor comprises a friction-enhancing surface structure for engaging adjacent tissue (Claim 17) | Appendix A, page 9, line 21 – page 10, line 1 |
| wherein the anchor comprises at least one barb for piercing a wall of a tissue adjacent the mitral valve annulus (Claim 18) | Appendix A, page 10, lines 1-2 |
| wherein the guidewire lumen is in a monorail design with respect to the implant (Claim 20) | Appendix A, page 41, lines 7-9 |
| wherein the flexible member is slideable for selectively adjusting a curvature of the implant in the remodeling configuration (Claim 21) | Specification, Figures 2A and 2B; Appendix A, page 8, lines 19-20 |

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| wherein the delivery catheter comprises a control mechanism for selectively adjusting a curvature of the implant (Claim 22) | Appendix A, Figure 10 |
| a rotational coupler along a proximal end portion of the implant that applies tension to the flexible member so as to change the implant to the second, remodeling configuration (Claims 22 and 23) | Appendix A, pages 36-38; claim 6 |
| wherein, when the implant is positioned in the coronary sinus in the first flexible configuration, and the forming member is advanced distally with respect to the coronary sinus, the curvature of the implant changes, thereby altering a shape of the mitral valve annulus (Claims 24 and 37) | Appendix A, page 24, lines 16-19 |
| wherein, when the implant is positioned in the coronary sinus in the first flexible configuration, and the forming member is advanced distally with respect to the implant, the curvature of the implant changes, thereby altering a shape of the mitral valve annulus (Claims 25 and 38) | Appendix A, page 24, lines 16-19 |
| wherein, when the implant is positioned in the coronary sinus, and the forming member is retracted proximally with respect to the implant, the curvature of the implant changes, thereby altering a shape of the mitral valve annulus (Claim 26) | Appendix A, page 24, lines 16-19 |
| wherein the forming member is flexible (Claim 27) | Specification, Figures 2A and 2B; Appendix A, page 8, lines 19-20 |

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| wherein the forming member is coupled to the control mechanism (Claims 28 and 34) | Appendix A, Figure 10 |
| the forming member resides at least partially in the implant (Claim 29) | Appendix A, Figure 2 |
| the forming member is slidable with respect to the implant (Claim 30) | Specification, Figures 2A and 2B; Appendix A, page 8, lines 19-20 |
| an implant, movable between a first configuration, for delivery to a coronary sinus, and a second configuration, for changing a shape of a mitral valve annulus (Claim 31) | Appendix A, page 13, lines 16-23 |
| a control mechanism for adjusting a curvature of the implant (Claim 31) | Appendix A, Figure 10 |
| a forming member, coupled to the implant, the forming member extending longitudinally along at least a portion of the implant (Claim 31) | Appendix A, Figure 10 |
| wherein the proximal part of the coronary sinus comprises the proximal one-third of the coronary sinus, and the distal part of the coronary sinus comprises the distal one-third of the coronary sinus (Claim 32) | Appendix A, Figure 1 |
| wherein the forming member is flexible (Claim 33) | Appendix A, Figure 2 |

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| wherein the forming member resides at least partially in the implant (Claim 35) | Specification, Figures 2A and 2B |
| wherein the forming member is slideable with respect to the implant (Claim 36) | Specification, Figures 2A and 2B |
| wherein, when the implant is positioned in the coronary sinus, and the forming member is retracted proximally with respect to the implant, the curvature of the implant changes, thereby altering a shape of the mitral valve annulus (Claim 39) | Appendix A, page 24, lines 16-19 |
| wherein, when the implant is positioned in the coronary sinus, and the forming member is advanced distally with respect to the implant, a radius of the curvature of the implant increases, thereby improving coaptation of leaflets of the mitral valve (Claim 40) | Appendix A, the paragraph bridging pages 39-40 |

Accordingly, Alferness et al. is not prior art to claims 1-3, 6, 12-14-18, and 20-40 of this Application, and Applicant respectfully requests withdrawal of the anticipation and obviousness rejections based on Alferness et al.

Solem et al. (USPAP 2001/0018611)

The Examiner rejected claims 1, 2, 6, and 12 as allegedly anticipated by Solem et al., and he rejected claim 3 as allegedly obvious over Solem et al.

Claim 1 is amended to recite that "when the implant is positioned in the coronary sinus, and the forming member is advanced distally with respect to the coronary sinus, the curvature of

the implant changes, thereby altering a shape of the mitral valve annulus." Support for this amendment is found in, for instance, paragraph [0042].

Nowhere does Solem et al. teach or suggest a system comprising an implant for mitral valve remodeling, and a forming member, coupled to the implant and extending longitudinally along at least a portion of the implant, wherein, when the implant is positioned in the coronary sinus, and the forming member is advanced distally with respect to the coronary sinus, the curvature of the implant changes, thereby altering a shape of the mitral valve annulus.

Because Solem et al. does not teach or suggest all of the limitations of claims 1-3, 6, and 12, as amended, Solem et al. does not anticipate the claims, nor does it establish *prima facie* obviousness against the claims. Applicant therefore respectfully requests withdrawal of the anticipation and obviousness rejections based on Solem et al.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests favorable action on this application. If any questions remain, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

Any remarks in support of patentability of one claim should not necessarily be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not necessarily be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully reserves the right to traverse any of the Examiner's rejections or assertions, even if not discussed herein. Applicant respectfully reserves the right to challenge later whether any of the cited references are prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present Application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant reserves the right to contest later whether a proper reason exists to combine prior art references.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1225 (PVI-5813CP2CP1CP1CON2), and please credit any excess fees to such deposit account.

Respectfully submitted,

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